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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,251	02/24/2004	Stanley W. Olson JR.	02-125 (US02)	2722

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/786,251	Applicant(s) OLSON ET AL.	
	Examiner Jerry Cumberledge	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 48-65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/24/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-54, 56-58 and 60-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Margulies et al. (US Pat. 6,679,890).

Margulies et al. disclose a method for delivering implant material into tissue using a cannula comprising a cannula body (Fig. 2b, ref. 20) having a first opening (Fig. 5a, ref. 23) (column 4, lines 50-52) and a second opening (Fig. 2b, ref. 60) proximal to the first opening, and a plunger (Fig. 1, ref. 40) slidably disposed within a lumen of the cannula body (column 5, lines 40-42), the method comprising: inserting the cannula body (Fig. 2b, ref. 20) into a distal section of a tissue (column 5, lines 36-39); perfusing the implant material out of the first opening into the tissue (column 5, lines 45-50); proximally displacing the plunger from a first position distal to the first opening into a second position between the first and second openings (column 5, lines 51-53); and perfusing the implant material out of the second opening into the tissue while the plunger is in the second position (column 5, lines 51-53). The method further comprises severing a distal portion from a proximal portion of the cannula member (column 5, lines

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64-67). The method further comprises separating a distal portion from a proximal portion of the cannula member (column 5, lines 64-67). The implant material is longitudinally perfused out of the cannula body through the first opening (column 5, lines 45-50), and transversely perfused out of the cannula body through the second opening (column 5, lines 51-53). The cannula body further comprises a third opening proximal to the second opening (Fig. 2b, ref. 60), the method further comprising: proximally displacing the plunger into a third position between the second and third openings (column 5, lines 51-53); and perfusing the implant material out of the third opening into the tissue while the plunger is in the third position (column 5, lines 51-53). The implant material is bone cement (column 7, lines 18-21). The tissue is bone tissue (column 4, lines 37-39).

Margulies et al. disclose a method for delivering implant material into tissue using a cannula comprising a cannula body (Fig. 2b, ref. 20) having a proximal end (Fig. 2b, near ref. 26), a distal end (Fig. 22, near ref. 30), one or more openings (Fig. 2, refs. 23 and 60), the method comprising: inserting the cannula body into tissue (column 5, lines 36-39); perfusing the implant material out of the one or more openings into the tissue (column 5, lines 45-50)(column 5, lines 51-53); and separating the proximal end from the distal end of the cannula body (column 5, lines 64-67). The implant material is bone cement (column 7, lines 18-21). The tissue is bone tissue (column 4, lines 37-39). The one or more openings comprises a plurality of openings axially spaced from each other (Fig. 2, refs. 23 and 60), the method further comprising perfusing the implant material out of the plurality of openings into the tissue (column 5, lines 45-53). The cannula

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further comprises a plunger (Fig. 1, ref. 40) configured to be slidably disposed in a lumen of the cannula body (column 5, lines 40-42), and the one or more openings comprises a first opening (Fig. 2, ref. 23) and a second opening (Fig. 2, refs. 60) proximal to the first opening, the method further comprising: proximally displacing the plunger from a first position distal to the first opening into a second position between the first and second openings (column 5, lines 51-53); and perfusing the implant material out of the second opening into the tissue while the plunger is in the second position (column 5, lines 51-53). Separating the proximal end from the distal end of the cannula body comprises detaching the cannula body by applying a shearing or twisting force (column 5, lines 64-67). Separating the proximal end from the distal end of the cannula body comprises unscrewing the proximal end from the distal end (column 4, lines 62-64). The method further comprises implanting the distal end of the cannula body within the tissue (column 5, lines 36-37). The distal end of the cannula body is composed of a biocompatible material (column 6, lines 37-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margulies et al. (US Pat. 6,679,890) in view of Reiley et al. (US Pat. 6,248,110 B1).

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Margulies et al. disclose the claimed method except for the bone tissue being a vertebral body.

Reiley et al. disclose a method for delivering implant material into tissue using a cannula (column 1, lines 53-65), where the tissue can be either a vertebral body (Fig. 39D) or other bones of the body (column 6, lines 3-8) and the method is used to treat fractures or other conditions of bone systems (column 1, lines 35-38).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the method of delivering implant material into tissue using a cannula of Margulies et al. in the vertebra as taught by Reiley et al., in order to treat fractures or other conditions of bone systems (column 1, lines 35-38).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

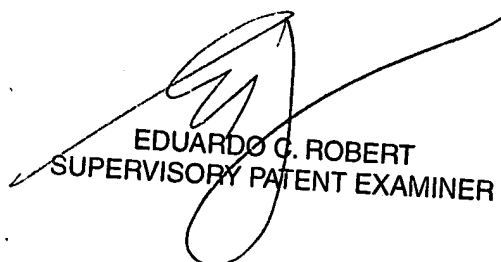
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER